Food and Drug Administration, HHS

- (2) No. 064847 for use of product described in paragraph (a)(2) of this section.
- (c) Conditions of use in horses—(1) Amount. 1 to 2 grams of phenylbutazone per 500 pounds of body weight, not to exceed 4 grams daily.
- (2) *Indications for use*. For relief of inflammatory conditions associated with the musculoskeletal system.
- (3) Limitations. Use a relatively high dose for the first 48 hours, then gradually reduce to a maintenance level of the lowest level capable of producing the desired clinical response. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 84762, Dec. 23, 1980, as amended at 58 FR 29777, May 24, 1993; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997; 68 FR 43926, July 25, 2003; 72 FR 60550, Oct. 25, 2007; 77 FR 4897. Feb. 1, 2012]

§520.1720d Phenylbutazone gel.

- (a) Specifications. Each 30 grams of gel contains 4 grams of phenylbutazone.
- (b) Sponsor. See No. 061623 in \$510.600(c) of this chapter.
- (c) NAS/NRC status. The conditions of use are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in §514.111 of this chapter, but may require bioequivalency and safety information.
- (d) Conditions of use in horses—(1) Amount. 1 to 2 grams of phenylbutazone per 500 pounds of body weight, not to exceed 4 grams daily.
- (2) *Indications for use*. For relief of inflammatory conditions associated with the musculoskeletal system of horses.
- (3) Limitations. Use a relatively high dose for the first 48 hours, then gradually reduce to a maintenance level at the lowest level capable of producing the desired clinical response. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[50 FR 13561, Apr. 5, 1985, as amended at 50 FR 49372, Dec. 2, 1985; 55 FR 8462, Mar. 8, 1990; 66 FR 14073, Mar. 9, 2001; 68 FR 4915, Jan. 31, 2003]

§520.1720e Phenylbutazone powder.

- (a) Specifications—(1) Each 1.15 grams (g) of powder contains 1 g phenylbutazone.
- (2) Each 10 g of powder contains 1 g phenylbutazone.
- (b) *Sponsors*. See sponsor numbers in §510.600(c) of this chapter.
- (1) No. 027053 for use of product described in paragraph (a)(1) of this section
- (2) No. 057699 for use of product described in paragraph (a)(2) of this section.
- (c) Conditions of use in horses—(1) Amount. Administer 1 to 2 g (1 to 2 level scoops, using the scoop provided) per 500 pounds of body weight on a small amount of palatable feed, not exceed 4 g per animal daily.
- (2) Indications for use. For the relief of inflammatory conditions associated with the musculosketetal system.
- (3) Limitations. Do not use in horses intended for human consumption. Federal law prohibits the extralabel use of this product in female cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 27956, May 18, 2007]

§520.1760 Phenylpropanolamine.

- (a) *Specifications*. Each chewable tablet contains 25, 50, or 75 milligram (mg) phenylpropanolamine hydrochloride.
- (b) Sponsors. See No. 055246 in \$510.600(c) of this chapter.
- (c) Conditions of use in dogs—(1) Amount. Administer 2 mg/kg of body weight twice daily.
- (2) *Indications for use.* For the control of urinary incontinence due to urethral sphincter hypotonus in dogs.
- (3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[77 FR 15961, Mar. 19, 2012]

§520.1780 Pimobendan.

- (a) *Specifications*. Each chewable tablet contains 1.25, 2.5, or 5 milligrams (mg) pimobendan.
- (b) *Sponsor*. See No. 000010 in §510.600(c) of this chapter.
- (c) Conditions of use in dogs—(1) Amount. Administer orally at a total daily dose of 0.23 mg per pound (0.5 mg